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| 10/079,452 | 02/20/2002 | Christopher F. Claiborne | 20832Y | 7378 |

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| EXAMINER |
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RAO, DEEPAK R

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| ART UNIT | PAPER NUMBER |
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1624

DATE MAILED: 06/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/079,452

Applicant(s)
Claiborne et al.

Examiner
Deepak Rao

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 20, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 ☒ are pending in the application.
- 4a) Of the above, claim(s) 3-8, 10-39, 41-43, and 45-47 ☒ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 9, 44, and 48-52 ☒ are rejected.
- 7) ☒ Claim(s) 40 is/~~are~~ objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 6) ☐ Other:

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DETAILED ACTION

Claims 1-52 are pending in this application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20, 31-41, 43-46 and 48-52, drawn to compounds of formula (I) wherein the **NonAr** ring is a nonaromatic 6-membered ring containing 1 nitrogen ring atom (e.g., piperidine), corresponding composition and method of use, classified in class 546, subclass 184+.
- II. Claims 1, 21-25, 42 and 48-52, drawn to compounds of formula (I) wherein the **NonAr** ring is a nonaromatic 5-membered ring containing 1 nitrogen ring atom (e.g., pyrrolidine), corresponding composition and method of use, classified in class 548, subclass 400+.
- III. Claims 1, 26-30, 43, 47 and 48-52, drawn to compounds of formula (I) wherein the **NonAr** ring is an aza bicyclo octane ring, corresponding composition and method of use, classified in class 546, subclass 112+.
- IV. Claims 1 and 48-52, drawn to compounds of formula (I) wherein the **NonAr** ring is a nonaromatic is other than those of Groups I-III above, corresponding composition and method of use, classified in class 544/546/548, various subclasses.

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The inventions are distinct, each from the other because of the following reasons:

Groups I-IV are drawn to structurally dissimilar compounds. They are made independently and used independently. They would be expected to raise different issues of patentability if a compound of Group I, consisting of piperidiny1 group as the **NonAr** ring moiety were anticipated, the anticipatory reference would not necessarily render obvious the compounds of Groups II-IV or vice-versa. They are not art recognized equivalents, they are classified separately and require separate burdensome searches both in the literature and patent databases.

Because these inventions are distinct for the reasons given above and as shown by their classification, have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claims are generic to a plurality of disclosed patentably distinct species comprising the species disclosed in the application. In addition to the election of a single group, applicant is required under 35 U.S.C. 121 to elect **a single disclosed species falling within the elected group**, even though this requirement is traversed.

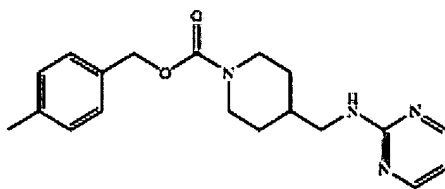
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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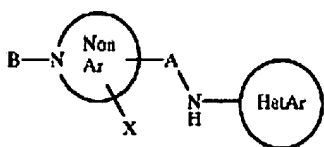
During a telephone conversation with Mr. Mitul Desai on May 6, 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-20, 31-41, 43-46 and 48-52 and the species of Example 17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-30, 42 and 47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The elected species of Example 17 (depicted below for convenience)



represents a compound of formula (I) wherein:



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HetAr is pyrimidinyl;

A is -C₁alkyl- (i.e., -CH₂-);

NonAr is 1-piperidin-4-yl; and

B is aryl(CH₂)-O-C(O)- wherein aryl is 4-methylphenyl.

Claims 1-2, 9, 40, 44 and 48-52 read on the elected species.

The guidelines in MPEP § 803.02 provide that upon examination if prior art is found for the elected species, the examination will be limited to the elected species.

Content of MPEP § 803.02 is provided here for convenience:

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the non-elected species would be held withdrawn from further consideration. As in the prevailing practice, **a second action on the merits on the elected claims would be final.**

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

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The elected species identically was not found in the prior art search and the search was expanded to the subgenus of formula (I) wherein:

HetAr is pyrimidinyl (optionally substituted as recited in claim 1);

A is -C₀₋₁alkyl- (i.e., absent or -CH₂-);

NonAr is 1-piperidin-4-yl; and

B is aryl(CH₂)-O-C(O)- or aryl(CH₂)₁₋₃- wherein aryl is phenyl,

and art was found. As per the guidelines of MPEP § 803.02, the Markush-type claims were examined to the extent of the searched subgenus. Claims 3-8, 10-20, 31-39, 41, 43, 45 and 46 drawn to compounds of formula (I) wherein **HetAr**, **A**, **NonAr** and **B** are other than those stated for the above subgenus are additionally withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected species. Claims 1-2, 9, 40, 44 and 48-52 are examined to the extent readable on the subgenus as indicated above.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 9, 44 and 48-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

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1. The claims recite "A compound or pharmaceutically acceptable salts thereof" wherein the plural recitation of "salts" is not proper Markush language. The claim reads better if replaced with -- or a pharmaceutically acceptable salt thereof --. Appropriate amendment is suggested. (Claims 40 and 44 recite the above suggested proper Markush language).
2. In claim 44, in the structural formulae of many of the species the -N- following the HetAr group has an open valency, see the species disclosed in pages 199-200. As the base claim recites a -NH- group, all species should also have the same group.

Claims not particularly addressed above are included here because they are dependent claims and do not further resolve the above issues.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 9, 48, 49 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaper et al., WO 99/51589. The instantly claimed compounds read on the compounds of the reference, see the reference disclosed compounds in Table 1, pages 45-49, particularly, compounds 38-43. The reference also teaches composition comprising the compounds and

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further teaches that the compounds are useful in the field of veterinary medicine, see page 37.

The intended use recitation in the composition claims is not given any patentable weight.

(U.S. 6,300,333 cited in PTO-892 belongs to the same patent family as WO 99/51589 and relied upon as the English equivalent of WO'589).

2. Claims 1 and 48-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Bosmans et al., WO 97/43279. The instantly claimed compounds read on the reference disclosed compounds, see structural formula (I) and the species of compound No. 11 in Table 1, page 17. The reference teaches that the compounds are useful as pharmaceutical therapeutic agents for a variety of diseases including depression, etc., see page 9. The reference inherently teaches the treatment of pain as it discloses that the compounds are useful in many vascular and inflammation disorders.

3. Claims 1 and 48-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al., WO 97/19065. The instantly claimed compounds read on the reference disclosed compound, see the compound N-(1-benzylpiperidin-4-yl)-2-chloro-4-pyrimidinamine in page 58, line 17.

4. Claims 1 and 48-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhu et al., Chem. Abstract 95:150311 (1981). The instantly claimed compounds read on the reference compound of RN 79278-72-1, see the enclosed copy of the CAPLUS computer search report.

5. Claims 1 and 48-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Moragues et al., Chem. Abstract 94:24760 (1980). The instantly claimed compounds read on reference

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disclosed compounds, see the compounds disclosed (e.g., RN 76167-42-5) in the enclosed copy of the CAPLUS computer search report.

Duplicate Claims

Applicant is advised that should claim 48 be found allowable, claims 49-50 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 49-50 recite the intended use of the composition of claim 48.

Allowable Subject Matter

Claim 40 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form limiting to the species wherein **HetAr** is pyrimidinyl and including all of the limitations of the base claim and any intervening claims.

Claim 44 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action; limiting to the species wherein **HetAr** is pyrimidinyl and to include all of the limitations of the base claim and any intervening claims.

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Receipt is acknowledged of the Information Disclosure Statement filed on July 23, 2002 and a copy is enclosed herewith.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Deepak Rao
Primary Examiner
Art Unit 1624

June 3, 2003